A COMPARATIVE EVALUATION OF THE LARYNGEAL MASK AIRWAY – PROSEAL AND TRACHEAL INTUBATION FOR LAPAR0SCOPIC CHOLECYSTECTOMY

Dissertation submitted in partial fulfillment of the requirements for the degree of

M.D (*anaesthesiology*)

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CERTIFICATE

This is to certify that the Dissertation entitled "**A COMPARATIVE EVALUATION OF THE LARYNGEAL MASK AIRWAY – PROSEAL AND TRACHEAL INTUBATION FOR LAPAR0SCOPIC CHOLECYSTECTOMY"** is the bonafide original work of Dr.SENTHIL KUMAR.K. in partial fulfillment of the requirement for MD anaesthesiology examination of the Tamilnadu Dr. MGR Medical University to be held in March 2009.

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DECLARATION

I, **Dr. K. SENTHIL KUMAR,** solemnly declare that dissertation titled, "**A COMPARATIVE EVALUATION OF THE LARYNGEAL MASK AIRWAY – PROSEAL AND TRACHEAL INTUBATION FOR LAPAR0SCOPIC CHOLECYSTECTOMY"** is the bonafide work done by me at Govt. .Stanley medical college and hospital during the period August 2007 to August 2008 under the expert guidance and supervision of Prof. Dr. P. Chandrasekar M.D. D.A.

The dissertation is submitted to the Tamilnadu Dr. MGR Medical university towards partial fulfillment of requirement for the award of MD Degree in anaesthesiology.

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CONTENTS

SL.NO.	TITLE	PAGE NO.
1	INTRODUCTION	1
2	AIM OF THE STUDY	3
3	LARYNGEAL MASK AIRWAY(LMA)	4
4	PROSEAL LMA	6
5	LAPAROSCOPIC SURGERY	11
6	REVIEW OF LITERATURE	13
7	MATERIALS AND METHODS	23
8	OBSERVATION AND RESULTS	27
9	DISCUSSION	46
10	SUMMARY	50
11	CONCLUSION	51

INTRODUCTION

Tracheal intubation and controlled ventilation is the gold standard for the anaesthetic management of a patient undergoing laparoscopic cholecystectomy. The problems common to laproscopic procedures are due to carbon dioxide insufflations. The raised intra-abdominal pressure causes a potential danger of gastric regurgitation and pulmonary aspiration.The Classic LMA is not a very popular device for positive pressure ventilation for fear of gastric distension, aspiration of gastric contents and inadequate ventilation.

The ProSeal laryngeal mask airway (PLMA) introduced in 2000AD, is a modification of the Classic Laryngeal Mask Airway (CLMA). The cuff of the PLMA is specially designed with an aim to provide a more effective seal around the glottic opening for providing positive pressure ventilation and the drain tube provides a bypass channel for regurgitated gastric contents and also a nasogastric tube can be passed through the drain tube to deflate and aspirate the gastric contents that is essential in laparoscopic surgeries.(59)

Nowadays open surgeries are progressing to minimally invasive keyhole surgery i.e laparoscopic surgeries. These laparoscopic surgeries need pneumoperitoneum which will cause increased intra abdominal pressure, elevation of diaphragm, alteration in patient positioning. All these will have a impact in ventilator parameters.

Hence a prospective randomized study was designed to compare the use of the PLMA and Endo tracheal tube as a ventilatory device in patients undergoing elective laparoscopic cholecystectomies under general Anaesthesia with controlled ventilation.

AIM OF THE STUDY

The aim of the study was to compare the Proseal Laryngeal Mask Airway with Endo tracheal tube in laparoscopic cholecystectomy based on the:

Ventilation parameters: oxygen saturation

End tidal carbondioxide

Minute ventilation

Airway pressure

Ease of insertion of the device and nasogastric tube.

Trauma.

LARYNGEAL MASK AIRWAY

The Laryngeal Mask Airway was designed by ARCHIE.I.J. BRAIN between 1981- 87.Original purpose was to reduce the need for more invasive means of airway management while offering a more reliable alternative to the face mask, at the same time less stressful compared to the endotracheal tube.

The Laryngeal Mask Airway is nothing but a supraglottic airway device that provides and maintain end to end seal at the laryngeal inlet and allows gentle intermittent positive pressure ventilation.

The standard Laryngeal Mask Airway consists of a curved tube(shaft) to match the oropharyngeal anatomy connected to an elliptical mask at an angle of 30^0(60) . The airway tube is semi rigid to facilitate atraumatic insertion and semitransparent so that condensation and regurgitation are visible. The mask is oval shaped and consists of a cuff which is inflatable through an inflation tube and self sealing pilot ballon. The inner aspect of the ballon is called the bowl. There are two vertical bars at the junction of the tube and the mask, the mask aperture bars, which is designed to prevent epiglottis from falling back into the aperture of the tube. A black line runs longitudinally along the posterior aspect of the tube to orient it after placement. A standard 15 mm connector is present at the machine end of the tube.

Uses of LMA(32):

Originally LMA was used as an emergency airway device during resuscitation then it was used as an airway device in patients with difficult airway. Nowadays it is used as a conduit for ventilation during anaesthesia especially in day care surgeries. LMA is also used as a tracheal intubation assist device.

Advantages of LMA over endotracheal tube(4) :

The advantages includes more rapid placement without laryngoscopy. Airway manipulation is less that gives a better hemodynamic response. It is better tolerated than an endotracheal tube decreasing the chance of post operative sorethroat and incidence of coughing during emergence. The overall anaesthetic requirement will be less.

Advantages of LMA over Face mask :

LMA provides convenience of hands free, can give positive pressure ventilation and less chances of injuries to the eyes.

PROSEAL LARYNGEAL MASK AIRWAY

The Proseal laryngeal mask airway (PLMA)(60) introduced in 2000 AD, is a modification of Classic LMA. It consists of airway tube, bowl and cuff. The airway tube is reinforced with similar caliber to an equivalent reinforced/flexible LMA (fLMA). Modifications compared to the CLMA are: 1) larger and deeper bowl with no grille, 2) posterior extension of the mask cuff; 3) drainage tube running parallel to the airway tube and exiting at the mask tip; 4) integral silicone bite block; 5) anterior pocket for seating an introducer or finger during insertion. The bowl lacks the 'semi rigid shell' of the CLMA.

The aims of the modifications are: 1) avoidance of gastric inflation during controlled ventilation; 2) less need for tight occlusion of the upper esophageal sphincter (UES) by the mask tip in the event of regurgitation, because of the presence of the drainage tube (DT); 3) opportunity to pass an orogastric tube (OGT); 4) channeling of regurgitated stomach contents. Changes were also designed to improve airway seal. The presence of the DT port also allows rapid diagnosis of mask misplacement.

When the PLMA is positioned correctly, the airway orifice lies over the glottis and the DT tip lies behind the cricoid cartilage at the origin of the esophagus. Airway and DT each form uninterrupted routes from these sites to outside the mouth. This functional separation of the respiratory and gastrointestinal tracts is important in understanding potential advantages of the PLMA over the CLMA and other supraglottic airway devices (SADs). In this regard one might consider the PLMA to act as an 'artificial larynx', rather than simply an airway tube.

The PLMA is reusable and recommended product life is 40 sterilizations. Not all protein material can be removed by routine cleaning of laryngeal masks and this raises theoretical concerns over cross-infection risk. Interestingly there are no cases of bacterial, viral or prior disease transferred between patients by reuse of a sterilized LMA. Recently, cleaning cLMAs with a technique including potassium permanganate was reported to eliminate residual protein on 80% of LMAs and reduce protein load on the remaining 20%. Residual protein on the devices was reduced by an estimated 91%. Similar reductions in protein load would be anticipated with the PLMA.

AVAILABLE PLMA SIZES:

SIZE

LENGTH
CM

INFLATION VOLUME

PATIENT WEIGHT (kg)

1.5
2
2.5
3
4
5

10
11
12.5
16
16

18

7 ml
10ml
14 ml
20 ml
30 ml
40 ml

5 to 10
10 to 20
20 to 30
30 to 50
50 to 70
70 to 100

Preparation:

The cuff is fully deflated by pressing the hollow side down onto a clean surface, with two fingers pressing the tip flat. The deflated cuff should be free from wrinkles. A lubricant is applied to the posterior surface of the cuff.

Placement:

After inducing the patient with appropriate drugs, the LMA can be placed with or without muscle relaxants. The patient is placed in supine sniffing position. The head is held in slight extension by having the nonintubating hand stabilizing the occiput. The jaw is allowed to fall open or held open by an assistant. The device is held between the thumb and index finger as close as possible to the junction of the tube and the mask. The distal tip of the deflated cuff pressed against the hard palate and LMA is advanced using the index finger to guide the tube over the back of the tongue. The tube is advanced until a characteristic resistance is felt as the upper oesophageal sphincter is engaged. The hand is taken out while holding the shaft with other hand. Without holding the tube the cuff is inflated with appropriate amount of air to achieve a proper seal. Correct placement produces a leak-free seal with the mask tip wedged against the upper oesophageal sphincter. If positioned correctly at least 50% of the bite block usually disappears beyond the upper incisors. Where the entire bite block is visible the device is almost certainly misplaced. Inward force while the PLMA is secured reduces extrusion and misplacement. A lubricated Orogastric tube (OGT) can be passed through the DT when indicated. Slight resistance may be noted as the

OGT negotiates the distal end of the DT and passes the UES. Inability to pass an OGT indicates mask misplacement.

Modified techniques of insertion:

The PLMA can be inserted with the cuff partially inflated, with laryngoscope assisted, through lateral approach or by anterior traction of tongue.

Signs of correct PLMA placement:

Correct placement of PLMA can be confirmed by Slight outward movement of the tube on inflation., Presence of a small oval swelling in the neck around the thyroid and cricoid area, No cuff visible in the oral cavity and Expansion of chest wall on bag compression.

PLMA removal :

The **P**LMA is tolerated well even in lighter planes of anaesthesia and can be left in place during emergence. The PLMA should not be removed in lighter planes. It should be removed after full return of airway reflexes.[12,13,14]

LAPAROSCOPIC SURGERY-ANAESTHETIC IMPLICATIONS

Physiologic changes during laparoscopy (54) :

Three major forces that uniquely alter the patients cardio respiratory physiology during Laparoscopy:

Increase in intra abdominal pressure.

Effects of patient positioning.

Carbon dioxide.

Cardiovascular changes:

The cardiovascular changes due to pnemoperitoneum and Hypercarbia are increased heart rate, increased mean arterial pressure, increase in systemic vascular resistance, increase in central venous pressure and decreased cardiac output. Hyper carbia directly stimulates the myocardial irritability and arrythmogenicity and also causes myocardial depression.

Respiratory changes:

The major respiratory changes due to pnemoperitoneum includes Decreased functional residual capacity, Decreased vital capacity, Restricted diaphragmatic excursion, Decreased compliance, Raised

airway pressure, Endobronchial migration of ETT, Cephalad displacement of mediastinum.

Hypercarbia(12) :

Hyper carbia causes Acidosis, Arrhythmia, Hypertension, Increase in heart rate, Increase in intracranial pressure and CO_2 embolism.

Pneumoperitoneum(39) :

Peritoneal insufflations of carbon dioxide increases intra-abdomial pressures and causes Bowel ischemia, Gastric egurgitation, Compression of inferior vena cava, Decreased venous return, Decreased cardiac output.

Increase in intra thoracic pressure, Pnemothorax, Barotrauma, Atelectasis, Nausea and vomiting.

Reverse Trendelenberg Position(39) :

The head up position during laparoscopic cholecystectomy results in decreased venous return, cardiac output, right atrial pressure and pulmonary capillary wegde pressure.

REVIEW OF LITERATURE

Between 1981 and 1987, Dr.Archie Brain developed a new way of linking the artificial and anatomical airways. This new concept, known as the laryngeal mask airway (LMA) was different from other forms of airway management.(1)

Combining the advantages of a noninvasive face mask and the more invasive tracheal tube, the laryngeal mask airway was created to fill an important functional gap that existed between the standard methods of airway control that were in use then.

Being the latest in a succession of attempts to fill the gap between the face mask and tracheal tube, the LMA was initially received with skepticism in anaesthesia community. Some considered that the face mask and tracheal tube was all that was necessary for the practice of good anaesthesia and the LMA was a device exclusively meant for the management of the difficult airway.

Originally the device was recommended as a better alternative to the face mask. But ever since its development the LMA has challenged the assumption that the tracheal intubation is the only acceptable way to maintain a clear airway and provide positive pressure ventilation. Infact the first clinical series of Dr. Brain included 16 cases of gynecologic laparoscopy with positive pressure ventilation.

Since its commercial introduction in 1988, use of LMA during surgery has exploded. The LMA is available in 80 countries and has been used in estimated 150 million surgical procedures. There are now over 3000 publications pertaining to LMA .

The main complications of using LMA relate to the airway seal pressure (inflation pressure of its cuff). This inflation pressure which less than the tracheal tube cuff pressure, results in escape of gas around the cuff that lead on to gastric distension, pulmonary aspiration of gastric contents and inadequate ventilation.

In 2000, Dr. Archie Brain introduced a variant of the Classic LMA, LMA – Proseal by adding a drain tube in addition to the airway tube. Also it has a posterior cuff to provide effective seal. The inventor's aims of the modifications are: 1) avoidance of gastric inflation during controlled ventilation; 2) less need for tight occlusion of the upper esophageal sphincter (UES) by the mask tip in the event of regurgitation, because of the presence of the DT; 3) opportunity to pass an orogastric tube (OGT); 4) channeling of regurgitated stomach contents.

Devitt JH, Wenstone R, Noel AG, O'Donnel MP; anaesthesia 1995 [17]

Since the utility of LMA during positive pressure ventilation was yet to be determined they designed a study to assess whether significant leaks occurred with positive pressure ventilation and if leaks were associated with gastro oesophageal insufflation. They concluded that ventilation with LMA was safe and adequate if airway resistance and pulmonary compliance are normal. They also concluded that gastro oesophageal insufflations of air will become a problem only in the presence of increased airway pressure.

Brimacombe JR; Can J Anaesthesia 1995[4]

A meta-analysis on randomized prospective trials comparing the LMA with other forms of airway management to determine if the LMA offered any advantages over the tracheal tube of face mask. Advantages over the tracheal tube included, increased speed and ease of placement by inexperienced personnel, increased speed of placement by anaesthetists, improved hemodynamic stability at induction and during emergence, minimal increase in intra ocular pressure following insertion, reduced anaesthetic requirement for airway tolerance, lower frequency of coughing during emergence and lower incidence of sore throat in adults.

Verghese C, Brimacombe JR ; Anaes Analg ; 1996.[11]

A survey of LMA usage conducted by them to provide information about safety and efficacy with special emphasis on controversial issues such as positive pressure ventilation, prolonged anaesthesia, laparoscopic and non laparoscopic intra abdominal surgery. During the two year study

period, of the 39,824 patients who underwent general anesthesia, 11,910 (29.9%) patient airways were managed with the LMA. They came to a conclusion that LMA technique is safe and effective for both controlled and spontaneous ventilation. They also concluded that the use of LMA for gynaecologic laparoscopy and procedures >2 hours was safe.

Voyagis GS, Papakalou EP;Acta Anaesthesiol Belg; 1996[52]

The use of LMA size 3 and 4, and endotracheal tube 8.0mm was studied comparatively to determine the adequacy of respiratory function during positive pressure ventilaion by applying a series of given peak inspiratory pressures of 10.0, 12.5, 15.0, 17.5, 20.0, 30.0 cm H_2O. They found that higher values of tidal volumes were expired via LMA compared with endotracheal tube when a given peak pressures of less than 20 cm H_2O was applied. They also found that LMA as opposed to endotracheal tube secured normocapnia during positive pressure ventilation with low peak inspiratory pressures.

Bures E, Fusiardi J, Lanquetot H; Acta Anaesthesiol scand; 1996[34]

During laparoscopic cholecystectomy the arterial-end-tidal gradient(Pa-$ETCO_2$) has been variously shown to be unchanged, increased, decreased or even negative. The goal of this study was to evaluate Pa-$ETCO_2$, and to determine the proper contribution of ventilator adequacy in regard to the increase of $PETCO_2$. They concluded that only exogenous CO_2 loading, and not ventilator adequacy, could explain such increase in $PETCO_2$ and $PaCO_2$, in cases of limited CO_2 insufflating pressure in ASA 1-2 patients.

Buniattian AA, Dolbneva EL; 1997

This study was aimed at assessing the air tightness of the airways during the use of a LMA under muscle paralysis and positive pressure ventilation of the lungs with carboperitoneum during laparoscopic cholecystectomy. They concluded that though pneumoperitoneum caused increase in $ETCO_2$, $PaCO_2$, inspiratory pressures and decreases in breathing volume and lung compliance the combination of laryngeal mask, neuromuscular blockers and positive pressure ventilation may be successfully and safely used in clinical practice.

Ho BY, Skinner HJ, Mahajan RP; Anaesthesia; 1998[44]

This study was aimed to evaluate whether or not the use of intermittent positive pressure ventilation via the LMA is associated with a higher risk of gastro-oesophageal reflux when compared with intermittent ventilation via a tracheal tube in patients undergoing day case gynaecological laparoscopy. They found no evidence to suggest that the use of intermittent use of positive pressure ventilation via the laryngeal mask increases the risk of gastro-oesophageal reflux in patients undergoing elective day case gynaecological laparoscopy.

8 PP Bapat and C Verghese Anesthesia & Analgesia,1997[20]

They studied the incidence of regurgitation in 100 patients undergoing elective gynecological laparoscopies under general anesthesia with intermittent positive pressure ventilation using a laryngeal mask airway (LMA). Patients ingested methylene blue capsules 10-15 min before induction of anesthesia. Fiberoptic examination revealed the vocal cords or cords and posterior or anterior epiglottis in 96 and no trace of dye in 99 patients. One patient regurgitated dye immediately after induction, and the stain was seen on the LMA after removal. The remaining 99 LMAs were not stained. Thirty patients were randomly selected for fiberoptic examination of the laryngopharynx before neuromuscular block was antagonized. Methylene blue staining did not occur in any of these patients. In 91 patients with complete pH data, regurgitation (pH < 4.0) did not occur. The 95% confidence limit for a true probability of regurgitation in this study is 0.041 or a true rate of regurgitation of less than 4.1%. A larger study would be required to possibly demonstrate a lower incidence of regurgitation. This study confirms the clinical impression that the incidence of regurgitation during laparoscopies with a LMA is extremely low.

Latorre F, Eberle B, Weiler N, Minert R, Anaes Analg ;1998[22]

Since the potential risk of LMA is an incomplete mask seal causing gastric insufflations or oropharangeal air leakage, the objective of the study was to assess the incidence of LMA malpositions by Fibre optic laryngoscopy, and to determine their influence on gastric insufflation and oropharangeal air leakage. Fibre optic verification of mask position revealed sub optimal placement of LMA in 40% of cases. They concluded that such malpositioning considerably inceased the risk of gastric air insufflation when LMA is used with positive pressure ventilation.

Fassoulki A, Paraskeva A, Karabinis G, Acta Anaest Belg 1999[45]

They studied the ventilatory adequacy and respiratory mechanics during positive pressure ventilation via LMA as compared with tracheal tube. They concluded that, in patients with normal airway pressure and compliance, positive pressure ventilation using LMA is comparatively effective with the use of endotracheal tube.

Roger Maltby , Michael T, Beriault, Neil C Watson ; CJA 2000[48].

They studied gastric distension and ventilation during laparoscopic cholecystectomy comparing LMA- Classic vs tracheal intubation. They concluded that positive pressure ventilatinon with correctly placed LMA- Classic of appropriate size permits adequate pulmonary ventilation and

that gastric distension occurred with equal frequency with either airway device.

Lu PP, Brimacombe J, Yang C, Shyr M, Br J Anaesthesia 2002[33]

They did the study to test the hypothesis that the proseal laryngeal mask airway is a more effective ventilatory device than the Classic laryngeal mask airway for laproscopic cholecystectomy. They concluded that the proseal LMA is a more effective ventilator device for laproscopic cholecystectomy than Classic

LMA. Further they recommended against the use of Classic –LMA for laparoscopic cholecystectomy.

Malty JR, Beriaylt MT, Watson NC, Liepert DJ, CJA 2002[5].

The study was to compare LMA proseal with endotracheal tube with respect to pulmonary ventilation and gastric distension during laparoscopic cholecystectomy. They conclded that a correctly seated LMA- Proseal or endotracheal tube provided equally effective pulmonary ventilation without clinically significant gastric distension in all non-obese patients.

Natalini G, Lanza G, Rosana A, Dell'Agnolo P, J clin naes 2003[14]

They compared the airway seal and frequency of sorethroat with the LMA-Proseal and Standard LMA during laparoscopic surgery. They concluded that that LMA – proseal and the LMA Classic show similar airtight efficiency during laparoscopy.

Malty JR, Beriaylt MT, Watson NC, Liepert DJ, Fick GH; CJA 2003[25]

They conducted a study to compare LMA classic, LMA proseal with endotracheal tube with respect to pulmonary ventilation and gastric distension during gynaecologic laparoscopy. They came to a conclusion that correctly placed LMA-classic or LMA- Proseal is as effective as an endotracheal tube for positive pressure ventilation without clinically important gastric distension in non-obese and obese patients.

Viira D, Myles PS, Anaes Intensive care 2004[7]

They did a literature search and found limited evidence to support or refute the use LMA in setting of gynaecologic laparoscopy. They however found that the reported incidence of aspiration or more serious morbidity associated with the use of LMA in laparoscopic surgery is very low.

Chmielewski C, Snyder-Clickett S;Anas and Analge 2004[19]

The purpose of this article was to discuss the benefits, safety, and efficacy of the LMA and identify the risks and misconceptions associated with LMA s when used with positive pressure ventilation. They concluded that when compared to other airway adjuvants, however , the laryngeal mask airway is a safe, effective means of delivering ventilation under anaesthesia.

Piper SN, TRiem JG, Rohm KD, Maleck WH, Scholhorn TA; 2004[38]

The aim of this study was to assess the practicality of the proseal LMA during laparoscopic surgery with carboperitoneum compared to endotracheal intubation. They conclded that the proseal LMA is a convenient and practical approach for anaesthesia in patients undergoing laparoscopic surgery.

MATERIALS AND METHODS

Study design:

This study was a randomized prospective comparative study.

Study setting and population:

After obtaining institutional ethical committee clearance, the study was conducted in 40 adult patients of either sex between the age group of 18-50 years belonging to ASA physical status 1 posted for elective laparoscopic cholecystectomy at Surgical Gastroenterology OT complex , Department of Anaesthesiology, Stanley medical college and Hospital, Chennai, from March 2008 to June 2008.

Inclusion criteria:

Adults of either sex,

Age between 18 and 50 years.

ASA physical status 1

Mallampatti Airway class I and II

Exclusion criteria:

Body mass index > 30 kg/m^2

Age below 18 and above 50 years

Mallampatti classification >II

Symtoms related to laryngopharyngeal abnormality.

Musculoskeletal abnormalities affecting the cervical vertebrae.

Study method:

After obtaining ethical committee approval, the patients were randomized into two groups.

Study group (Group P) : PLMA for airway management.

Control group(Group E): ETT for airway management.

All patients fasted overnight. They were given anti aspiration prophylaxis with Tab. Ranitidine 150 mg on the night before and Inj. Ranitidine 50 mg i.v and Inj. Metoclopramide 10 mg i.v 1 hr before surgery. Patients were premedicated with Inj. Glycopyrrolate 0.2 mg IM 1 hour before surgery.

Intravenous access obtained in the nondominant hand. After placement of routine monitoring devices viz pulse-oximetry, non invasive blood pressure monitor and Electrocardiogram, preoxygenation was done for 3 mins with 100% oxygen 6 l/min with Mapleson A circuit. Inj. Fentanyl citrate 2mic/kg iv given followed by Inj. Popofol 2mg/kg i.v. After checking the the adequacy of bag and mask ventilation,Inj. Vecuronium Bromide 0.1 mg/kg iv given and the patient ventilated with N_2O and Oxygen with FiO_2 0.5 for 3 mins. Anaesthesia was in supine position with the patient's head on a standard pillow of 10 cms height.

Group P (PLMA):

For women size 3 PLMA was used and for men size 4 PLMA was used with recommended cuff volume. After applying a clear lubricant PLMA insertion was carried out as recommended by the manufacturer using index finger technique for insertion. The correct placement of the PLMA was confimed by square wave pattern capnograph trace, absence of leak on auscultation over epigastrium and adequate chest expansion at airway pressure 20 cm water during manual ventilation. Fixation was by tapping the LMA over the chin. A 16 G Ryles tube was passed through the drain tube and contents were aspirated.

Failed insertion attempt was defined as a removal of the device from the mouth. Three attempts were allowed before insertion was considered a failure.

Group E (ETT):

For women size 7.0 mm ID and for men size 8.0 mm ID ETT was used. Cuff inflated to provide airtight seal. Position was confirmed clinically and by capnography. After placement of the endotracheal tube, a 16 G Ryles tube was placed and the gastric contents aspirated.

For both the groups anaesthesia was maintained with Isoflurane in Oxygen and N_2O with FiO_2 0.33 administered through circle system with CO_2 absorption. Fresh gas flows were kept at 6l/min. Neuromuscular

blockade was maintained with vecuronium bromide 0.15 mg/kg. After the surgical was over, procedure residual blockade was reversed with Inj. Glycopyrrolate 0.01 mg/kg and Inj. Neostigmine 0.05 mg/kg i.v.

Ventilation parameters were initially set at a tidal volume of 10ml/kg at a rate of 15 breaths/min. Intraoperatively the minute ventilation was adjusted to maintain an $ETCO_2$ between 35-40 mm of Hg. Abdominal insufflation pressure were limited to 12 mm of Hg..

Oxygenation was considered as a failure if SPO2 fell below 90%[33]. Ventilation was considered sub optimal if ETCO2 was >45 mm of Hg and failure if ETCO2 was >55mm of Hg [40]. These patients will be intubated with appropriate size ETT for further anaesthetic management and these cases will be excluded from the study.

Patients were shifted to PACU and monitored post-operatively**.**

PARAMETERS OBSERVED :

The parameters observed in this study parameters related to ventilation viz Oxygen saturation, Endtidal carbondioxide, Minute ventilation and Airway pressure, Ease of insertion of the device and nasogastric tube, duration of CO_2 insufflation, duration of anaesthesia and post extubation problems.

OBSERVATION AND RESULTS

The study was conducted in Surgical gastroenterology OT complex in Stanley medical college and hospital. The study was conducted in 40 patients of either sex belonging to ASA physical status 1. They are divided into two groups, Group P (study group) and Group E (control group).

The patients in both the groups were compared using Students "t" test for measured variables and Fischer's exact test for discrete variables. Chi square test was used to compare the sex differences. The level of statistical significance was at P value < 0.05

DEMOGRAPHIC DATA

The demographic data as seen in the table below was comparable in both the groups with respect to age, weight, height and BMI. In this study 75% of patients were females in the study group while 30% were males in the control group.

	Group	N	Mean	Std.deviation	Student t test
Age	P	20	33.85	8.002	t=0.28 p=o.78
	E	20	33.15	7.942	(NS)
	P	20	152.3	6.383	t=1.03 p=0.3
HEIGHT	E	20	154.25	5.447	(NS)
	P	20	51.95	6.89	t=0.17 p=0.85
WEIGHT	E	20	51.6	5.43	(NS)
BMI	P	20	22.25	1.410	t=1.34 p=0.19
	E	20	21.5	2.065	(NS)

BMI- Body Mass Index.   NS- Not Significant.

The average age of the patients in the study group was 34$\pm$8 years, whereas in the control group it was 33$\pm$8 years. There was no statistically significant difference between the two groups. ($p>0.05$).

The average body mass index of the patients in the study group was 22$\pm$1 kg/m^2, whereas in the control group it was 21$\pm$2kg/m^2. There was no statistically significant difference the two groups. ($p> 0.05$)

Sex

	Group P	Group	Total
Males	5	6	11
Females	15	14	29
Total	20	20	40

There was no statistically significant difference between the two groups based on the distribution of sex characteristics. X^2=0.53 p= 0.46 (not significant).

INSERTION CHARACTERISTICS

TIME	GROUP	N	MEAN	SD	P VALUE(S/NS)

DEVICE	P	20	14.05	1.503	0.852 (NS)
	E	20	13.09	1.848	
NGT	P	20	10.05	1.145	0.0001 (S)
	E	20	14.8	2.587	

NGT-Naso gastric tube SD-Standard deviation S-Significant
NS-Not significant.

The time taken for the placement of device was almost 14±2 seconds in both the groups showing no significant difference.P>0.05.

The time taken for insertion of NGT was 10±1 seconds in the study group while in the control group it was 15±3 seconds showing significant difference. P<0.05

INSERTION CHARACTERISTICS

SATURATION PERCENTAGE OF OXYGEN (SPO2)

	Group	N	Mean	Std. Deviation	Student t test
SPO2-B	P	20	99.00	.000	t=0.00 p=1.00 (NS)
	E	20	99.00	.000	
SPO2-P	P	20	99.00	.000	t=0.00 p=1.00 (NS)
	E	20	99.00	.000	

B - Baseline P - Pnemoperitoneum NS - Not Significant.

In both study and control group the oxygen saturation was 99% at baseline as well as during insufflation with COshowing no statistical significant difference ($p>0.05$)

END TIDAL CARBON DIOXIDE

	Group	N	Mean	Std. deviation	Student T test
ETCO2-BP	P	20	32.60	1.046	P=0.486
	E	20	32.30	1.592	NS
ETCO2-AP	P	20	36.35	1.565	P=0.453 NS
	E	20	36.80	2.142	
ETCO2-INC	P	20	3.75	0.519	P=0.66 NS
	E	20	4.50	0.550	

BP-Before pneumoperotoneum. AP-After pneumoperitoneum.

I-Increase. NS- Not significant.

The average baseline ETCO2 values were 32± 1mm Hg in the study group whereas in the control group it was 32±2 mm Hg showing no significant statistical difference.

The average ETCO2 values after pnemoperitoneum were 36±2 mm Hg in the study group whereas in the control group it was 37±2mmHg showing no significant statistical difference.

The average increase in ETCO2 values from baseline to pnemoperitoneum was 4±1 mm Hg in both the study and control group showing no significant difference.

END TIDAL CARBON DIOXIDE

MINUTE VENTILATION (V Min)

	Group	N	Mean	Std.dev	Student t-test
VMIN-BP	P	20	6.205	0.641	P=0.864
	E	20	6.165	0.815	NS

	P	20	7.310	0.815	P=0.873
VMIN-AP					
	E	20	7.256	1.239	NS
	P	20	1.105	0.174	P=0.44
VMIN-IN					NS
	E	20	1.091	0.424	

BP- before pneumoperitoneum; AP-After pneumoperitoneum

IN- Increase NS-Not significant.

The average base line minute ventilation was 6$\pm$ 0.5 l / min in the study group whereas in the control group it was 6$\pm$1 l, showing no significant difference.

The average base line minute ventilation after pneumoperitoneum was 7$\pm$1 litres in both the study group and the control group it, showing no significant difference.

The average increase in minute ventilation from baseline to pnemoperitoneum was 1$\pm$o.1 l in the study group whereas in the control group it was 1$\pm$0.5 l, showing no significant difference.

MINUTE VENTILATION

AIRWAY PRESSURE

	Group	N	Mean	Std. Deviation	Student t Test
AWP-BP	P	20	19.60	1.788	P=0.001
	E	20	16.80	1.196	S
AWP-AP	P	20	25.90	1.637	P=0.001
	E	20	23.45	1.586	S
AWP-I	P	20	6.30	1.538	P=0.66
	E	20	6.65	2.268	NS

BP-Before pnemoperitoneum. AP- After pnemoperitoneum.

S-Significant . AWP- Airway pressure.

The average baseline airway pressure was 20 ± 2 cm H_2O in the study group whereas in the control group it was 17 ± 2 cm H_2O, showing statistical significant difference ($p<0.05$).

The average airway pressure after pnemoperitoneum was 26$\pm$2 cm H_2O in the study group whereas in the control group it was 23$\pm$2 cm H_2O, showing statistical significant difference ($p<0.05$).

The average increase in airway pressure was 6$\pm$2 cm H2O both in the study group and the control group, showing no statistical significant difference ($p>0.05$).

AIRWAY PRESSURE

DURATION

Group	N	Mean	Std. Deviation	p-value

I-TIME	P	20	72.25	19.498	P=0.714 NS
	E	20	74.50	18.980	
A-TIME	P	20	89.35	17.936	P=0.704 NS
	E	20	92.50	17.554	

I-time: Insufflation time. A-Time: Anaesthesia Time

NS- Not significant.

The average insufflations time was 72±20 mins in the study group compared to 75±19 mins in the control group, showing no statistical significant difference.

The average anaesthesia time was 89±18 in the study group whereas it was 92±18 in the control group, showing no significant statistical difference.

CO_2 INSUFFLATION TIME

G 1- GROUP E, G2- GROUP P

ANAESTHESIA TIME

EVENTS RELATED TO EXTUBATION

Events	Case N=20	Control N=20	X^2 Fisher exact t test
Cough	2	4	P=0.66(NS)
Laryngospasm Bronchospasm	Nil	Nil	
Nausea and Vomiting	2	1	P=1.00(NS)
O_2 desaturation	Nil	Nil	

Trauma	2	Nil	P=0.48(NS)
Gasric regurgitation	Nil	Nil	

NS-Not significant

There was no significant difference between the two groups based on the events related to extubation. ($p>0.05$)

Coughing was more common in the ETT group.

EVENTS RELATED TO EXTUBATION

DISCUSSION

The PLMA is a new entrant to the family of LMA with some added features over the classic LMA. In this study, the PLMA was used for elective laparoscopic cholecystectomies. It was used for a maximum duration for 125 minutes.

PLMA can be inserted using either the introducer, index finger or the thumb. For the purpose of standardization, in this study the index finger technique was used for insertion for all the cases. In this study both PLMA insertion and traditional ETT intubation took 14 seconds. The PLMA was correctly placed in the first attempt in 19 cases while for one case two attempts were required. Endotracheal intubation was successful in all cases in the first attempt.

In this study there was no difficulty in passing nasogastric tube through the PLMA. Insertion of nasogastric tube through the nose was more time consuming and took 14.8(2.6) seconds in the ETT group as against 10(1.1) seconds in the PLMA group. The difference in this data is statistically significant and will be clinically important in patients with hypertension, ischaemic heart disease etc.

There was no fall in SPO_2 value in both the study and control group. The ventilation was adequate to maintain a saturation of 99% in

both the groups even after pneumoperitoneum was created. This was compared with Malby et al and Natalini et al. study where they have shown that maintenance of adequate oxygen saturation is possible with PLMA during laproscopic procedures.

The baseline $ETCO_2$ value was 32$\pm$ 1mm Hg in the study group as well as in the control group without any significant statistical difference. The value was increased to 36$\pm$2 mm Hg in the study group during CO_2 insufflation for laparoscopic surgeries whereas in the control group it was 37$\pm$2mmHg without any statistically significant difference. Malby et al and Natalini et al. also observes similar findings in their studyi and it has been clearly shown that the maintenance of $ETCO_2$ within the normal values was possible with PLMA during laparoscopic surgeries.

The average minute ventilation required during pnemoperitoneum for effective elimination of CO_2 and adequate oxygen saturation in this study was 7$\pm$1 litres in both the study group and the control group, showing no significant difference. The average increase in minute ventilation from baseline to pnemoperitoneum for effective elimination of CO_2 and adequate oxygen saturation in this study was 1$\pm$0.5 litres in both the study group and the control group. This was in concordance with the studies done by Malby et al and Buniattian et al.

The average baseline airway pressure was 20$\pm$2 cm of H_2O in the study group whereas in the control group it was 17$\pm$2cm of H_2O, showing statistically significant difference ($p<0.05$). During pnemoperitoneum the average airway pressure was 26$\pm$2 cm of H_2O in the study group whereas in the control group it was 23$\pm$2 cm of H_2O , showing significant difference ($p<0.05$).In this study the airway pressure showed a significant increase during insufflations within both the groups ($p=0.001$), in concordance with Brimacombe et al. After creating pneumoperitoneum the increase in airway pressure from baseline 6$\pm$2 cm H_2O both in the study group and the control group, showing no statistical significant difference ($p>0.05$) between the two groups which was in concordance with Malby et al, Natalini et al,and Brimacombe et al. In these studies the authors have shown that the increase in airway pressures did not exceed the recommended values in PLMA group and there is a significant increase in the airway pressures between the two groups both before and after pnemoperitoneum.

The incidence of events related to extubation did not show a significant difference between two groups. Coughing was more common in the ETT goup but this was not statistically significant ($p=0.69$) in concordance with Maltby et al. There was no cases of layngospasm or bronchopasm or Gastric regurgitation in both the groups. No untoward complications were noted in both the groups during the perioperative period.

SUMMARY

The comparative evaluation of the PLMA and tracheal intubation for laparoscpic cholecystecomy showed no significant difference between the two groups based on the demographic variables

The PLMA group maintained effective oxygen saturation similar to ETT group during pneumoperitoneum.

The ETCO2 values were within normal limits in both the groups during pneumoperitoneum and baseline.

The changes in minute ventilation required for effective pulmonary ventilation during pneumoperitoneum were similar between both the groups.

Significant increase in airway pressure both before and after pneumoperitoneum was seen in both the study and control group. This is to maintain adequate minute ventilation and gas exchange.

The duration of the surgical procedure was same in both the groups.

Regarding events related to extubation / PLMA removal there were no significant differences between the two goups.

CONCLUSION

In this study, the PLMA and the ETT show similar efficacy during laparoscopic surgery under general anaesthesia with controlled ventilation. The PLMA aids easy and rapid insertion of the nasogastric tube. Though there is an increase in airway pressure during laparoscopy in PLMA it does not exceeds 30 cm of H_2O, and it provides adequate pulmonary ventilation maintaining oxygen saturation and effective elimination of carbon dioxide similar to endotracheal tube. In this study it is concluded that, in patients with BMI < 30 kg/m^2 the Proseal Laryngeal mask Airway is safe as compared with Endotarcheal tube for laparoscopic cholecystectomy under General Anaesthesia with controlled ventilation.

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COMPARATIVE EVALUATION OF PLMA AND TRACHEAL INTUBATION IN LAPAROSCOPIC CHOLECYSTECTOMY

PROFORMA

NAME:

AGE/SEX:

IP NO:

WEIGHT: KG

HEIGHT: MS

BMI: KG/M^2

MPC:

PLMA/ETT:

Time taken for insertion of the device :

Time taken for placement of NGT :

MEAN	BASELINE	BEFORE PNEUMOPERITONEUM	AFTER PNEUMOPERITONEUM
SPO_2			
$ETCO_2$			
V min			

AWP

Insufflation time:

Anaesthesia time:

Emergence outcome:

	SPO2 %	$ETCO_2$ mm hg	CO_2 insufflation	TV	RR/ Min	Vmi L	Awp Cm H_2O	FGF L
Baseline								
1 min induction								
5								
10								
15								
20								
30								
40								
50								
60								
70								
80								
90								
100								
110								
120								
120								
130								